Guidance for RNIs when MHS is relying on an external IRB

Any RNIs received from the IRB of record must be submitted in the shell study using the "Report New Information" (RNI) function within 10 business days of receipt. Documentation from the IRB of record's decision must be attached to the RNI. For the following reportable event types, please provide the following information:

- If any determinations related to **non-compliance** at our site were made, then please provide documentation from the IRB of record if the non-compliance was deemed to be serious vs. non-serious and continuing vs. non-continuing. If there is a mention of a corrective action plan, then please provide the corrective action plan that was provided to the IRB of record. Last, if there were determinations made related to serious and/or continuing non-compliance, please provide information from the IRB of record regarding if they need to notify any federal agencies related to the non-compliance (e.g., if the study is federally funded or FDA-regulated).
- If any determinations related to **unanticipated problems or adverse events** at our site were made, then please confirm if the issue was deemed serious by the IRB of record (as well as if the event aligned with the reporting requirements for unanticipated problems and adverse events in the MHS IRB Reportable Events Guidance Document). If the event was deemed serious, then please provide information from the IRB of record regarding if they need to notify any federal agencies related to the event (e.g., if the study is federally funded or FDA-regulated).
- If there were any determinations related to **breaches of confidentiality** at our site, then please confirm if MHS Privacy has been made aware of this as well as if the IRB of record needs to notify any federal agencies related to this event (e.g., if the study is federally funded or FDA-regulated). IRB staff may also reach out to MHS Privacy to see if any additional information is needed from MHS Privacy related to this.
- If there were any **audit reports** from the IRB of record of our site, then please explain any corrective actions that were implemented as recommended by the IRB of record as well as if the IRB of record needs to notify any federal agencies related to this event (e.g., if the study is federally funded or FDA-regulated).
- If there were any **research subject complaints** from subjects at our site, then please clarify how this was resolved as well as if the IRB of record needs to notify any federal agencies related to this event (e.g., if the study is federally funded or FDA-regulated).
- If there were any **holds, suspensions, or terminations** of research by the sponsor, funding agency, or regulatory agency, then please confirm that all activities on the study have stopped at MHS as well as if the IRB of record needs to notify any federal agencies related to this event (e.g., if the study is federally funded or FDA-regulated).